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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,969	07/23/2003	Brent A. Johnson	17592 (AP)	1610
51957	7590	06/15/2007		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			EXAMINER SOROUSH, LAYLA	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,969	Applicant(s) JOHNSON, BRENT A.	
	Examiner Layla Soroush	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2007 has been entered. The original restriction election is carried over from the response to the office action mailed on June 6, 2006.

Claims 39-44 are pending. Claims 1-38 have been cancelled and claims 39-44 have been added.

Claim 44 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking.

Claims 39-43 are herein acted on the merits.

See rejections below:

Claim Rejections- 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shefer et al. (US 20030232091) in view Won et al. (US 5,955,109), Shalita et al. (Tazarotene gel is safe and effective in the treatment of acne vulgaris: a multicenter,

double-blind, vehicle-controlled study. *Cutis*. 1999 Jun; 63 (6):349-54), and Sefton (US 6262117—previously presented)

Shefer et al. teaches a controlled release system composition comprising a plurality of particles having retinol and other cosmetic, dermatological, and pharmaceutical active agents (p 16 [0187] claims 1 and 7). Active agents comprise one or more agents selected from the group inclusive of anti-acne agents and anti-wrinkle agents. Anti-acne agents are inclusive of antibiotics and antimicrobials such as benzoyl peroxide (p 8 [101]). Anti-wrinkle agents are inclusive of tazarotene (p 8-9 [103]). The composition particle or micro-sphere has a diameter of from about 0.1 to about 500 microns (p 17 claim 30). Suitable solid core materials for forming microspheres or particles of the present invention are inert nontoxic hydrophobic materials with a melting point range between about 30 degrees C and about 120 degrees C. Examples of hydrophobic materials include natural, regenerated, or synthetic waxes including: animal waxes such as beeswax, lanolin and shellac wax; vegetable waxes such as carnauba, candelilla, sugar cane, rice bran, and bayberry wax; mineral waxes such as petroleum waxes including paraffin; and microcrystalline wax, ozokrite wax, polyethylene wax, and mixtures thereof. Other hydrophobic materials which can be used in the present invention include wax and silicon copolymers, such as candelilla wax and silicone copolymer, ozokrite wax and silicon copolymers, beeswax and silicon copolymers, and the like. Other hydrophobic compounds which can be used in the present invention include: fatty acid esters such as cetyl palmitate, ethyl stearate, isopropyl myristate, and isopropyl palmitate; high molecular weight fatty

alcohols such as cetostearyl alcohol, cetyl alcohol, stearyl alcohol, and oleyl alcohol, solid hydrogenated castor and vegetable oils, hard paraffins, hard fats, and mixtures thereof... (p 6-7 [0089] and p 16 claim 2).

Shefer does not exemplify a composition comprising tazaroten and benzoyl peroxide.

Won et al. teaches in the background of the invention that retinoids rapidly degrade and lose activity in typically formulated creams, ointments, oils, and the like. "In addition, moderate to severe skin irritation frequently results from the use of these formulations." Won et al. has cured these deficiencies by inventing a novel encapsulate controlled release composition of retinoids.

Shalita et al. is solely used to show tazarotene is a retinoid that acts against several factors that contribute to acne vulgaris.

Sefton teaches in the background of the invention that "Benzoyl peroxide has been suggested for treating acne vulgaris. (See U.S. Pat. No. 4,387,107.) For many years, benzoyl peroxide has been proven to be a particularly powerful keratolytic and anti-seborrhic agent, as well as being endowed with antibacterial properties. Topical benzoyl peroxide compositions, including a vehicle to enhance the efficacy thereof, are known (See U.S. Pat. No. 4,411,893). Topical compositions of benzoyl peroxide combination with antibiotics are also known. (See U.S. Pat. Nos. 4,407,794; 4,692,329 and 4,387,107)

Peroxides, other than benzoyl peroxide, have been suggested for treatment of acne vulgaris, alone, or in combination with other compounds useful in treating acne

vulgaris. (See U.S. Pat. Nos. 4,607,101 and 4,906,617.) These peroxides are suggested as having certain advantages, e.g. stability over benzoyl peroxide. U.S. Pat. No. 4,671,956 identifies the problem of benzoyl peroxide decomposing coingredients in topical formulations to thereby cause itching upon application. It is suggested that this problem may be solved by including a sunscreen in the topical formulation to retard this decomposition effect of benzoyl peroxide." (col 1 lines 43-65)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Shefer et al. in making a composition comprising a multiplicity of solid particles containing tazarotene and benzoyl peroxide. The motivation to make such a composition is because (1) Shefer et al. teaches a controlled release system composition comprising a plurality of particles having retinol and other cosmetic, dermatological, and pharmaceutical active agents (p 16 [0187] claims 1 and 7). Active agents comprise one or more agents selected from the group inclusive of anti-acne agents and anti-wrinkle agents. Anti-acne agents are inclusive of antibiotics and antimicrobials such as benzoyl peroxide (p 8 [101]). Anti-wrinkle agents are inclusive of tazarotene (p 8-9 [103]). (2) Additionally, Shalita et al. teaches tazarotene is a retinoid that acts against several factors that contribute to acne vulgaris and (3) Won et al. teaches in the background of the invention that retinoids rapidly degrade and lose activity in typically formulated creams, ointments, oils, and the like. "In addition, moderate to severe skin irritation frequently results from the use of these formulations." (4) Sefton teaches in the background of the invention that "Benzoyl peroxide has been suggested for treating acne vulgaris and identifies the problem of

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benzoyl peroxide decomposing coingredients in topical formulations to thereby cause itching upon application. Therefore, a skilled artisan would have had reasonable expectation of successfully producing a composition with controlled, continuous release of effective levels of retinol and other active agents over an extended period of time useful in treatment of acne vulgaris.

Response to Arguments

Applicant's arguments filed 3/22/07 have been fully considered.

In view of Applicant's cancellation of claims 1-38 all the rejections made in the previous office actions are herewith withdrawn and Applicant's arguments are moot.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

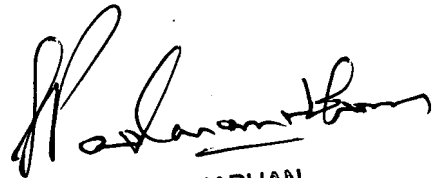
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER